REMARKS

Claim Status

Claims 18 and 23 have been amended to incorporate some of the limitations of claims 22 and 27, respectively. In particular, claims 18 and 23 have been amended to recite that the placement of the gel substance leads to the development of allodynia. No new matter is introduced.

Claims 22 and 27 have been cancelled.

As amended, claims 18, 20, 23 and 25 are currently pending.

35 U.S.C. § 112, First Paragraph, Rejection

Claim 27 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In response, some of the limitations (i.e., mammalian models exhibiting allodynia) of claim 27 have been incorporated into claim 23. Mammalian models exhibiting hyperalgesia and mammalian models exhibiting both allodynia and hyperalgesia have been deleted from claim 27, which has been cancelled. Upon the above amendments, this rejection is moot.

Claims 18, 20, 22, 23, 25 and 27 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicant respectfully traverses this rejection.

Applicant first notes that claim 19, a previously cancelled claim, was included in this rejection. It is believed that this inclusion was an error.

Claims 18 and 23 have been amended to incorporate the subject matters of claims 22 and 27, respectively, with the deletion of the phenotypic effect of hyperalgesia and phenotypic effect of both allodynia and hyperalgesia. Claims 18 and 23 as amended now recite that the placement of the gel substance leads to the development of allodynia, which is a phenotypic effect from the injected collagen. Claims 22 and 27 have since been cancelled. Consequently, the rejections of claims 18, 20, 22, 23, 25 and 27 under 35 U.S.C. § 112, first paragraph, as allegedly being non-enabled for a method or product wherein hyperalgesia is achieved and wherein no phenotypic effect occurs as a result of the injected gel substance should be withdrawn.

With respect to the issue relating to anterior and posterior tibial nerve, Applicant submits that a tibial nerve does not have an anterior and posterior tibial nerve division or branch; although the lower portion of the tibial nerve that passes behind the tibia may be referred to as the posterior tibial nerve in practice to differentiate the lower portion from the more proximal portion of the tibial nerve above the knee, as described in the present application (see paragraph [0025] of the publication) as well as in prior art publications. Applicant hereby attaches a copy of the cover page and pages 103, 105 and 109 of the book titled "The CIBA Collection of Medical Illustrations" as Exhibit A, which mentions no anterior or posterior tibial nerve during the discussion of the tibial nerve. One of ordinary skill in the art of mammalian anatomy would know that there is no such reference as anterior tibial nerve.

35 U.S.C. § 103 Rejection

Claims 18, 22, 23 and 27 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Reyna (ICLAS, Palma de Malloren, May 26-28, page 226, 1999). Applicant respectfully traverses this rejection.

As discussed in Applicant's previous response, Reyna discloses an open surgical method for generating a pain model, which is in direct contrast to the present invention claiming a non-surgical method for generating a pain model.

Applicant respectfully disagrees with the Examiner that one of ordinary skill in the art would have been motivated to perform the surgical method of Reyna and in the mean time, non-surgically introduce the gel substance into the tunnel surrounding the posterior tibial nerve, because Reyna's open surgical method differs greatly from the non-surgical method as presently claimed.

With Reyna's open surgical method, the area of the placement of the biocompatible substance is physically visualized by the practitioner, whereas in the present invention, the area of collagen placement is mentally visualized with kinesthetic techniques. Teachings regarding open surgical method would certainly not lead to practice of a non-surgical method, because totally different guidelines are observed in these two very different methods.

Additionally, Reyna does not mention a nerve tunnel, a lower portion of the tibial nerve behind the tibia, or precise placement of the biocompatible substance. Rather, Reyna teaches that a biocompatible substance was introduced near the nerve. The area of implied placement

disclosed in Reyna was the area that was surgically exposed and physically visualized, i.e., the lower thigh to the posterior popliteal region. This is the region just behind the knee.

With the opposite teaching of Reyna, Applicant asserts that one of ordinary skill in the art would not have produced the method and/or model as claimed in the present application. In fact, the Examiner previously agreed with Applicant's assertion by stating in the Advisory Action: "Amendment to the claims requiring that no surgical action occur in the claimed method would be sufficient to overcome the art rejection with respect to Reyna. Reyna taught surgical treatment of animals." Consequently, the rejection of claims 18, 22, 23 and 27 under 35 U.S.C. § 103 should be traversed.

Claims 20 and 25 stand rejected under 35 U.S.C. § 103 as being allegedly unpatentable over Reyna in view of Ford (Laryngoscope, Vol. 96, pages 1248-1257, 1986). Applicant respectfully traverses this rejection.

As discussed above, Reyna discloses an open surgical method for generating a pain model, which is in direct contrast to the present invention claiming a non-surgical method for generating a pain model.

Ford discloses injection of bovine collage into canine vocal folds to correct glottic insufficiency. Ford does not disclose a non-surgical method of generating an animal pain model. In fact, Ford uses collagen to treat an unpleasant physiological condition, rather than cause an unpleasant physiological condition such as pain. Ford further teaches that injectable collagen is

well tolerated (*See* ABSTRACT), whereas the present invention teaches that collagen is not well tolerated unless pain is the intended result.

It is well known in the art at the time the invention was made that biocompatible substances such as collagen are meant to minimize any immune response to prevent the development of any painful tissue conditions instead of causing pain. Many biocompatible substances are placed near nerves in many medical and surgical procedures without development of neurogenic pain. Thus, it would be against common knowledge for one of ordinary skill in the art to use collagen for producing a pain model at the time the present invention was made.

Furthermore, there is no suggestion or mentioning from Reyna and Ford, alone or combined, that collagen can be used to generate a persistent neurogenic pain model. Lacking correct guidance, even though one of ordinary skill in the art were motivated to combine the teachings of Reyna and Ford, he or she would not have been able to produce the present invention.

In view of the above remarks, Applicant asserts that Reyna in view of Ford does not render obvious the present invention as claimed. Accordingly, the rejection of claims 20 and 25 under 35 U.S.C. § 103 should be traversed.

CONCLUSION

In view of the foregoing amendment and remarks, it is respectfully submitted that this application is in condition for allowance.

The Examiner is invited to contact the undersigned agent at (713) 787-1512 with any comments or suggestions relating to the referenced patent application.

This paper is accompanied by a request for a two-month extension of time and authorization to charge Howrey Deposit Account No. 01-2508/13629.0002.NPUS00 for the appropriate fees. Should any additional fee be required for any reason in connection with this paper, the Commissioner is authorized to deduct said fees from the same deposit account.

Respectfully submitted,

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